

Article 1. ~~Shellfish Certificates~~ Definitions

Section 7706.01 Adverse Pollution Condition.

“Adverse pollution condition” means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that have historically resulted in elevated fecal coliform levels in a particular growing area.

Section 7706.02 Biotoxin or Marine Biotoxin.

“Biotoxin” or “marine biotoxin” means any poisonous compound produced by marine microorganisms and accumulated by shellstock, including but not limited to paralytic shellfish poisoning, amnesic shellfish poisoning, diarrhetic shellfish poisoning, and neurotoxic shellfish poisoning.

Section 7706.03 Conditionally Restricted

“Conditionally Restricted” means a classification used to identify a growing area which meets the criteria for the Restricted classification as defined in Section 112155 of the Health and Safety Code, except under certain conditions described in a hazard analysis and critical control point procedures plan.

Section 7706.04 Control Point or Critical Control Point.

“Control point” or “critical control point” means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

Section 7706.05 Critical Limit or Critical Control Limit.

“Critical limit” or “critical control limit” means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Section 7706.06 Depuration.

“Depuration” means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

Section 7706.07 Direct Marketing.

“Direct marketing” means the sale for human consumption of shellfish which 1) does not require depuration or relaying prior to sale or 2) has been subjected to depuration or relaying activities.

Section 7706.08 Fecal Coliform.

“Fecal coliform” means that portion of the coliform group of bacteria which will produce gas from lactose in a EC or A-1 multiple tube procedure liquid medium within 24 hours (± 2 hours) in a water bath maintained at 112 degrees Fahrenheit (44.5 degrees ± 0.2 degrees Centigrade).

Section 7706.09 Hazard Analysis.

“Hazard analysis” means the first step in developing hazard analysis and critical control point procedures that involves the identification of all significant hazards to the growing area. The hazard analysis is based on a sanitary survey of the growing area and surrounding shoreline and watershed.

Section 7706.10 Hazard Analysis and Critical Control Point Procedures.

“Hazard analysis and critical control point procedures” means a preventative system for ensuring food safety.

Section 7706.11 Hazard Analysis and Critical Control Point Procedures Plan.

“Hazard analysis and critical control point procedures plan” means a written document that delineates the formal procedures to be followed in the preventative system developed for ensuring food safety.

Section 7706.12 Operating Limits.

“Operating limits” means criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation from a critical control point.

Section 7706.13 Person.

“Person” means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, firm, corporation, limited liability company, or other entity. Person includes the federal government, the State, and any public or private entity.

Section 7706.14 Relay.

“Relay” means to transfer shellstock from a shellfish growing area classified as Restricted, Conditionally Restricted, or Approved or Conditionally Approved in a

closed status but meeting at least the water quality standards of a Restricted area, to a growing area classified as Approved or Conditionally Approved for the purpose of reducing pathogens as measured by the fecal coliform indicator group or reducing poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

Section 7706.15 Sanitary Survey.

“Sanitary survey” means the evaluation of all environmental factors, including actual and potential hazards, which have a bearing on the water and shellfish quality in a proposed or existing growing area.

Section 7706.16 Seed.

“Seed” means shellstock which is significantly less than market size and requires at least 180 days (6 months) of growing to reach market size.

Section 77406.17 Definition Shellfish.

For purposes of these regulations, the term “Shellfish” is hereby declared to mean and includes all varieties of oysters, clams, and mussels, geoducks, scallops, and other bivalve shellfish of concern as determined by the Department of Health Services.

Section 7706.18 Shellstock.

“Shellstock” means live molluscan shellfish in the shell.

Section 7706.19 Systematic Random Sampling Strategy.

“Systematic random sampling strategy” means a sampling strategy based on a random sampling plan established before field sampling begins.

Section 7706.20 Wet Storage.

“Wet storage” means the temporary storage, by a dealer, of shellstock from shellfish growing areas in the Approved classification or in the open status of the Conditionally Approved classification in containers or floats in natural or artificial bodies of water or in tanks containing natural or synthetic seawater.

Article 2. ~~Safety of Shellfish and Health of Employees~~ Shellfish Certificates

Section 7706.25 ~~Shellfish Bed Certificates Issuabled~~ by the ~~State Board of Public Health~~ Department of Health Services.

Any person, ~~firm, or corporation~~ engaged in the cultivating or harvesting of oysters, clams, ~~or geoducks~~, mussels, scallops, or other bivalve shellfish of concern as determined by the Department of Health Services for sale to the public for human consumption shall possess a valid certificate issued by the ~~State Board of Public Health~~ Department of Health Services.

Section 7706.30 Shellfish Growing Area Certificate.

(a) Any person engaged in growing or harvesting shellfish intended for sale for human consumption shall possess a valid Shellfish Growing Area Certificate issued by the Department of Health Services.

(b) The certificate shall be issued to the lawful grower or harvester and shall identify the location or facility where the growing and harvesting of shellfish are authorized.

(c) A Shellfish Growing Area Certificate shall be nontransferable.

Section 7706.31 Application for and Issuance of a Shellfish Growing Area Certificate.

(a) An application for a Shellfish Growing Area Certificate shall be submitted in a form acceptable to the Department of Health Services.

(b) An application shall contain:

(1) The name, address, and telephone number of the person making the application.

(2) A description of the proposed operation, including but not limited to the species of shellfish to be harvested, the source of the seed for each species of shellfish to be cultivated, the methods of culture and harvest, equipment used, and the projected annual quantity of harvest.

(3) A description of the location including the growing area name and lease designation, the latitude and longitude coordinates, expressed in degrees, of all bounding corners, and a map showing the location and boundaries of the proposed certified shellfish growing area.

(4) Written verification that the applicant has secured ownership, a lease, or other legal authorization to conduct commercial shellfish growing and/or harvesting operations in the proposed certified shellfish growing area.

(5) The application fee as prescribed in Section ____.

(6) A current hazard analysis as required in Article 3 of the growing area must be on file. The hazard analysis as required in Article 3 must contain sufficient data to prove that each area meets the requirements under Section

_____.

(c) An application for a Shellfish Growing Area Certificate is considered complete and is accepted for filing when all the prescribed information and the certificate fee are received by the Department of Health Services.

(d) The applicant shall abide by the conditions set by the Department of Health Services in the Shellfish Growing Area Certificate.

Section 7706.32 Expiration and Renewal of a Shellfish Growing Area Certificate.

(a) A Shellfish Growing Area Certificate shall be valid for:

(1) A period specified on the certificate not to exceed three years; and

(2) The specific growing and harvesting operations documented in the application.

(b) A certificate holder shall submit an application for renewal in accordance with Section ____ no later than 60 days prior to the expiration date on the current certificate. Late filing of an application will result in an additional charge of 25 percent of the renewal fee.

(c) A renewal application shall include a listing and description of any changes in the applicant's growing and harvesting operations that were not approved as a part of the existing certificate.

Section 7706.40 Shellstock Relaying Certificate.

(a) Any person engaged in the relaying of shellstock intended for sale for human consumption shall possess:

(1) A valid Shellfish Growing Area Certificate issued by the Department of Health Services; and

(2) A valid Shellstock Relaying Certificate issued by the Department of Health Services.

(b) The Shellstock Relaying Certificate shall be issued to the lawful grower or harvester named on the application and shall at a minimum include:

(1) The source, destination, and species to be relayed.

(2) A description of the shellstock deposition method.

(3) A description of the method used to maintain adequate separation between different lots of shellfish. The method employed shall be easily visible from any lateral direction and distinguishable from a distance of 500 feet.

(4) Requirements for records to be kept by the certified relayer. These requirements include but are not limited to:

(A) Recording the date of harvest from the Approved, Conditionally Approved, Restricted, or Conditionally Restricted area as determined by criteria in Article 4, the date of deposition in the Approved or Conditionally Approved area as determined by criteria in Article 4 for treatment, and the date of harvest for sale for human consumption.

(B) Recording the identification of the buyer of any relayed shellstock, the amount bought, and the date of purchase.

(C) Complete and accurate records shall be maintained for at least three (3) years by the grower and shall be made available for inspection by the Department of

Health Services or its agents during all reasonable hours. Upon request, these records shall be submitted to the Department of Health Services within seven (7) days.

(c) A Shellstock Relaying Certificate shall be valid only when issued for:

- (1) A specific relay activity; and
- (2) Not more than three years.

(d) A Shellstock Relaying Certificate shall be nontransferable.

Section 7706.41 Application for and Issuance of a Shellstock Relaying Certificate.

(a) An application for a Shellstock Relaying Certificate shall be submitted in a form acceptable to the Department of Health Services.

(b) An application shall at a minimum include:

(1) The name, address, and telephone number of the person making the application.

(2) The source of the shellstock for the relay operation, including but not limited to:

(A) Identification of the harvest area.

(B) Possession of a valid Shellfish Growing Area Certificate for the source location.

(C) Identification of the destination of the shellstock.

(D) Possession of a valid Shellfish Growing Area Certificate for the relay destination area.

(E) A description of the species to be relayed.

(3) A description of the shellstock deposition method.

(4) A written report of a species-specific contaminant reduction study that has been reviewed and approved by the Department of Health Services.

(5) A description of the method used to maintain adequate separation between different lots of shellfish. The method employed shall be easily visible from any lateral direction and distinguishable from a distance of 500 feet.

(6) The application fee as prescribed in Section ____.

(7) A current hazard analysis as required in Article 3 of the source and destination areas must be on file. The hazard analysis as required in Article 3 must contain sufficient data to prove that each area meets the requirements under Section ____.

(c) Receipt of an application for a Shellstock Relaying Certificate shall be deemed to occur on the date the application is received by the Department of Health Services.

(d) An application for a Shellstock Relaying Certificate is considered complete and is accepted for filing when an application form containing all the prescribed information and the certificate fee are received by the Department of Health Services.

Section 7706.42 Expiration and Renewal of a Shellstock Relaying Certificate.

- (a) A Shellstock Relaying Certificate shall be valid for:
- (1) A period specified on the certificate not to exceed three years; and
 - (2) The specific relaying activity documented in the application.
- (b) A certificate holder shall submit an application for renewal in accordance with Section ____ no later than 60 days prior to the expiration date on the current certificate. Late filing of an application will result in an additional charge of 25 percent of the renewal fee.
- (c) A renewal application shall include a listing and description of any changes in the applicant's relaying operation that were not approved as a part of the existing certificate.

Section 7706.50 Shellstock Seed Transplanting Certificate.

- (a) Any person engaged in the harvest of seed for transplanting in Approved or Conditionally Approved growing areas as determined by criteria in Article 4 shall possess a valid Shellstock Seed Transplanting Certificate issued by the Department of Health Services.
- (b) The certificate shall be issued to the lawful grower or harvester named on the application and shall at a minimum include:
- (1) The name, address, and telephone number of the person making the application.
 - (2) A description of the proposed operation, including:
 - (A) The species of shellfish to be harvested and transplanted; and
 - (B) A description of the location, including the latitude and longitude coordinates, expressed in degrees, of all bounding corners, and a map showing the location and boundaries of the proposed seed harvest area; and
 - (C) The methods of seed harvest and equipment used, and the projected quantity of harvest and transplanting.
 - (3) A description of the location of the transplant area, including the growing area name and lease designation, the latitude and longitude coordinates, expressed in degrees, of all bounding corners, and a map showing the location and boundaries of the transplant area.
 - (4) Written verification that the applicant has secured ownership, a lease, or other legal authorization to conduct seed harvesting operations in the proposed area.
 - (5) Verification that the applicant has a valid Shellfish Growing Area Certificate for an Approved or Conditionally Approved growing area as determined by criteria in Article 4.
 - (6) The application fee as prescribed in Section ____.
 - (7) A description of the method used to maintain adequate separation between different lots of seed, and between transplanted seed and marketable-sized shellstock. The method employed shall be easily visible from any lateral direction and distinguishable from a distance of 500 feet in any direction.
 - (8) Requirements for records to be kept by the operator that include:
 - (A) Recording the date of seed harvest from the Restricted or Prohibited area as determined by criteria in Article 4, the date of deposition in the Approved or

Conditionally Approved area as determined by criteria in Article 4, and the date of harvest for sale for human consumption.

(B) Recording the identification of the buyer of shellstock originating as transplanted seed, the amount bought, and the date of purchase.

(C) Complete and accurate records shall be maintained for at least three (3) years by the grower and shall be made available for inspection by the Department of Health Services or its agents during all reasonable hours. Upon request, these records shall be submitted to the Department of Health Services within seven (7) days.

(c) A Shellstock Seed Transplanting Certificate shall be nontransferable.

(d) A Shellstock Seed Transplanting Certificate shall be valid only when issued for:

- (1) A specific seed transplanting activity; and
- (2) Not more than three years.

Section 7706.51 Application for and Issuance of a Shellstock Seed Transplanting Certificate.

(a) An application for a Shellstock Seed Transplanting Certificate shall be submitted in a form acceptable to the Department of Health Services.

(b) An application shall at a minimum include:

(1) The name, address, and telephone number of the person making the application.

(2) A description of the proposed operation, including:

(A) The species of shellfish to be harvested and transplanted; and

(B) A description of the location, the latitude and longitude coordinates, expressed in degrees, of all bounding corners, and a map showing the location and boundaries of the proposed seed harvest area; and

(C) The methods of seed harvest and equipment used, and the projected annual quantity of harvest and transplanting.

(3) A description of the location of the transplant area, including the growing area name and lease designation, the latitude and longitude coordinates, expressed in degrees, of all bounding corners, and a map showing the location and boundaries of the transplant area.

(4) Written verification that the applicant has secured ownership, a lease, or other legal authorization to conduct seed harvesting operations in the proposed area.

(5) Possession of a valid Shellfish Growing Area Certificate for the Approved or Conditionally Approved growing area as determined by criteria in Article 4 to be used as the seed transplant destination area.

(6) The application fee as prescribed in Section ____.

(7) A description of the method used to maintain adequate separation between different lots of seed, and between transplanted seed and marketable-sized shellstock. The method employed shall be easily visible from any lateral direction and distinguishable from a distance of 500 feet in any direction.

(8) A current hazard analysis as required in Article 3 of the source and destination areas must be on file. The hazard analysis as required in Article 3 must contain

sufficient data to prove that each area meets the requirements under Section ____.

Section 7706.52 Expiration and Renewal of a Shellstock Seed Transplanting Certificate.

- (a) A Shellstock Seed Transplanting Certificate shall be valid for:
 - (1) A period specified on the certificate not to exceed three years; and
 - (2) The specific transplanting activity documented in the application.
- (b) A certificate holder shall submit an application for renewal in accordance with Section ____ no later than 60 days prior to the expiration date on the current certificate. Late filing of an application will result in an additional charge of 25 percent of the renewal fee.
- (c) A renewal application shall include a listing and description of any changes in the applicant's seed harvesting operation that were not approved as a part of the existing certificate.

Section 7706.60 Wet Storage Certificate.

- (a) Any person engaged in the wet storage of shellstock intended for sale for human consumption shall possess a valid Wet Storage Certificate issued by the Department of Health Services.
- (b) The certificate shall be issued to the lawful grower or harvester named on the application and shall at a minimum include:
 - (1) The source, destination, and species to be wet stored.
 - (2) A description of the wet storage method.
 - (3) A description of the method used to maintain adequate separation between different lots of shellfish. The method employed shall be easily visible from any lateral direction and distinguishable from a distance of 500 feet.
 - (4) Requirements for records to be kept by the certified wet storage operator, including recording the date of harvest from the Approved or Conditionally Approved area as determined by criteria in Article 4, the date of deposition in the wet storage area, and the date of harvest for sale for human consumption.
 - (5) Complete and accurate records shall be maintained for at least three (3) years by the grower and shall be made available for inspection by the Department of Health Services or its agents during all reasonable hours. Upon request, these records shall be submitted to the Department of Health Services within seven (7) days.
- (c) A Wet Storage Certificate shall be valid only when issued for:
 - (1) A specific wet storage activity; and
 - (2) Not more than three years.
- (d) A Wet Storage Certificate shall be nontransferable.

Section 7706.61 Application for and Issuance of a Wet Storage Certificate.

- (a) An application for a Wet Storage Certificate shall be submitted in a form acceptable to the Department of Health Services.
- (b) An application shall at a minimum include:
 - (1) The name, address, and telephone number of the person making the application.
 - (2) The source of the shellstock for the wet storage operation, including but not limited to:
 - (A) Identification of the harvest area.
 - (B) Possession of a valid Shellfish Growing Area Certificate for the source location.
 - (C) Identification of the wet storage site.
 - (D) Possession of a valid Shellfish Growing Area Certificate for the wet storage site, if the wet storage site is an Approved or Conditionally Approved growing area.
 - (E) A description of the species to be wet stored.
 - (3) A description of the shellstock deposition method.
 - (4) A description of the method used to maintain adequate separation between different lots of shellfish. The method employed shall be easily visible from any lateral direction and distinguishable from a distance of 500 feet.
 - (5) The application fee as prescribed in Section ____.
- (c) The application for a Wet Storage Certificate shall include a current hazard analysis as required in Article 3 that contains sufficient data to prove that each area meets the requirements under Section ____.

Section 7706.62 Expiration and Renewal of a Wet Storage Certificate.

- (a) A Wet Storage Certificate shall be valid for:
 - (1) A period specified on the certificate not to exceed three years; and
 - (2) The specific wet storage activity documented in the application.
- (b) A certificate holder shall submit an application for renewal in accordance with Section ____ no later than 60 days prior to the expiration date on the current certificate. Late filing of an application will result in an additional charge of 25 percent of the renewal fee.
- (c) A renewal application shall include a listing and description of any changes in the applicant's wet storage operations that were not approved as a part of the existing certificate.

Section 7706.90 Grounds for Denial of a Shellfish Growing Area Certificate, Shellstock Relaying Certificate, Shellstock Seed Transplanting Certificate, or Wet Storage Certificate.

The Department of Health Services may deny any application for a certificate issued under this Article, or application for renewal of such certificate, upon finding that the applicant:

- (a) Has committed an act involving dishonesty, fraud, or deceit in the filing of the application for the certificate, or;

- (b) Has provided false or misleading information and/or records about a harvesting location and/or plant facilities, or;
- (c) Is not in compliance with any regulation adopted pursuant to Section 110065 or 112165 of the Health and Safety Code, or;
- (d) Has a facility or personnel not in compliance with Chapter 5 or Chapter 8 of Division 21, or Chapter 10 of Division 22, of the Health and Safety Code, or any regulations adopted pursuant to these acts, or;
- (e) Has been convicted of a crime (for purposes of this section, a conviction includes a plea of nolo contendere, and a crime means any felony as described in the Penal Code and/or any misdemeanor as described in Sections 111825 and 112240 of the Health and Safety Code), or;
- (f) Has commissioned an act of unprofessional conduct, including, but not limited to, any of the following:
 - (1) Gross incompetence;
 - (2) The commission of any act involving dishonesty or corruption, whether or not the act is committed in connection with a certificate;
 - (3) Falsification of any records and/or labels;
 - (4) Harvesting from a closed or restricted area;
 - (5) Knowingly making or signing an application, document, or label which falsely represents the existence of a state of facts;
 - (6) Failure to comply with any of the requirements of Chapter 5 or Chapter 8 of Division 21, or Chapter 10 of Division 22, of the Health and Safety Code, or any regulations adopted pursuant to these acts;
 - (7) Failure to comply with any of the conditions attached to a certificate issued by the Department of Health Services;
 - (8) The removal, sale, or disposal of a detained or embargoed food without permission of an authorized agent of the Department of Health Services, or the court;
 - (9) Failure to grant access to authorized agents of the Department of Health Services to any vehicle, growing area, processing facility, storage building, or holding container likely to hold shellfish;
 - (10) Failure to maintain required records or to allow authorized agents of the Department of Health Services to review and copy required records.

Section 7706.91 Processing of Certificate Applications.

- (a) Applications must be filed at the designated office of the Department of Health Services on a form provided by the Department of Health Services and must be accompanied by any required fee as provided for in Section ____.
- (b) The maximum period of time in which the Department of Health Services will notify an applicant in writing that an application is complete and accepted for filing, or deficient and if deficient what specific information or documentation is required to complete the application, is as follows:
 - (1) Shellfish Growing Area Certificate – 30 days.
 - (2) Wet Storage Certificate – 30 days.
 - (3) Shellstock Relaying Certificate – 30 days.

- (4) Shellstock Seed Transplanting Certificate – 30 days.
- (c) During the last two years, the minimum, median, and maximum certificate processing times of applications from the date of receipt of an application until notification to the applicant that the application is complete or deficient, were as follows:
- (1) Minimum – 30 days.
 - (2) Median – 30 days.
 - (3) Maximum – 30 days.
- (d) Upon acceptance of a completed application by the Department of Health Services, the applicant shall conduct, develop, and complete a hazard analysis and critical control point procedures as required in Article 3. The hazard analysis and critical control point procedures as required in Article 3 must be approved by the Department of Health Services prior to issuance of the certificate.

Section 7706.92 Fees for a Shellfish Growing Area Certificate, Wet Storage Certificate, Shellfish Relaying Certificate, or Shellfish Seed Transplanting Certificate.

- (a) A nonrefundable fee of one thousand dollars (\$1,000) shall accompany an initial application for a Shellfish Growing Area Certificate.
- (b) A nonrefundable fee of five hundred dollars (\$500) shall accompany an initial application for a Wet Storage Certificate.
- (c) A nonrefundable fee of five hundred dollars (\$500) shall accompany an initial application for a Shellstock Relaying Certificate.
- (d) A nonrefundable fee of one thousand dollars (\$1,000) shall accompany an initial application for a Shellstock Seed Transplanting Certificate.
- (e) A nonrefundable fee of two hundred dollars (\$200) shall accompany an application for renewal of a Shellfish Growing Area Certificate.
- (f) A nonrefundable fee of two hundred dollars (\$200) shall accompany an application for renewal of a Wet Storage Certificate.
- (g) A nonrefundable fee of 100 hundred dollars (\$200) shall accompany an application for renewal of a Shellstock Relaying Certificate.
- (h) A nonrefundable fee of two hundred dollars (\$200) shall accompany an application for renewal of a Shellstock Seed Transplanting Certificate.

Section 7707 Shellfish Plant Certificate Issuable by the State Board of Public Health Department of Health Services.

Any person, ~~firm, or corporation~~ operating a plant engaged in culling, shucking, packing or repacking fresh oysters, clams or mussels for sale to the public for human consumption shall hold a valid certificate issued by the ~~State Board of Public Health~~ Department of Health Services.

Section 7708.10 Authority of ~~State Board of Public Health~~ Department of Health Services to Revoke or Suspend Certificate.

Each certificate so issued shall be revocable or subject to suspension by the ~~State Board of Public Health~~ Department of Health Services if for any reason the safety of the shellfish as an article of food is not assured or if the standards set forth herewith are not maintained at all times.

Section 7708.20 Penalties.

Any person who violates any provision of this Article shall be subject to penalties pursuant to Chapter ____ of the Health and Safety Code.

~~Section 7709 Expiration and Renewal of Certificates.~~

~~A certificate issued under these regulations shall be valid for a period not to exceed one year and shall expire on February 15th of each year. An application for renewal of a certificate shall be made by January 1st of each year if an applicant desires to continue to hold a certificate. No certificate can be transferred.~~

~~Section 7711 Types of Certificates.~~

~~Shellfish certificates issued hereunder shall be of the following classifications:~~

- ~~(a) Shellfish beds and shellfish stock derived therefrom for human consumption.~~
- ~~(b) Shellfish culling, shucking, packing, and repacking plants and shucked shellfish produced therefrom for human consumption.~~
- ~~(c) A "limited" certificate may be granted as provided under Section 7744.~~

~~Section 7712 Application for Certificate.~~

~~The applicant for a certificate to operate in either of the classifications described above shall file with the State Department of Public Health a written request accompanied by a detailed description of the shellfish beds or shellfish handling plants and a map showing the location of the beds or facilities. With the application shall be filed a description of the proposed source or sources of shell or shucked stock. He shall also file with the State Department of Public Health an agreement to comply with each and all of these regulations.~~

~~Section 7713 No Shellfish Grown in the State of California to Be Sold or Distributed Unless Certified.~~

No shellfish grown in the State of California shall be sold or distributed except from growing areas that have been approved and have been granted a valid certificate by the ~~State Board of Public Health~~ Department of Health Services under these regulations. Shellfish shall not be sold or distributed

from growing areas in other states unless each lot of shellfish obtained therefrom bears a certificate number designating a certificate of cleanliness and safety issued by the State Department of Health of the state in which the shipment originates acceptable to the California ~~State Department of Public Health~~ Department of Health Services.

Section 7714 No Shucked Shellfish to Be Sold or Distributed Unless Certified.

No shucked shellfish shall be sold or distributed except where such shellfish have been handled in plants for which a certificate has been issued by the ~~State Board of Public Health~~ Department of Health Services under these regulations. Shucked shellfish from other states shall not be sold or distributed unless each lot of shucked shellfish obtained therefrom bears a certificate number designating a certificate of cleanliness and safety issued by the State Department of Health of the state in which the shipment originates acceptable to the California ~~State Department of Public Health~~ Department of Health Services.

Article 3. ~~Records~~ Requirements for Hazard Analysis and Critical Control Point Procedures

Section 7715.10 Hazard Analysis Required.

(a) A hazard analysis shall be required prior to:

(1) The harvest of shellstock for human consumption.

(2) The classification of a growing area as Approved, Conditionally Approved, Restricted, or Conditionally Restricted as determined by criteria in Article 4.

(b) A hazard analysis shall not be required to classify growing areas as Prohibited as determined by criteria in Article 4.

Section 7715.11 Sampling Plan Required for Hazard Analysis.

If the Department of Health Services determines that a hazard analysis is warranted for evaluation or reevaluation of an existing or proposed growing area, the applicant, grower, or harvester shall develop a sampling plan in accordance with Section _____. The sampling plan must be approved by the Department of Health Services prior to conducting, developing, and completing a hazard analysis and critical control point procedures.

Section 7715.12 Hazard Analysis and Critical Control Point Procedures Determination.

(a) The hazard analysis and critical control point procedures shall be based on the data, results and recommendations of the following:

(1) A hazard analysis, based on a sanitary survey comprised of a shoreline and watershed survey in accordance with Section _____.

(2) Establishment of critical control points for the existing or proposed growing area hazards identified in the shoreline and watershed survey. The critical control points are based on the existing and potential preventive measures identified in the hazard analysis.

(3) Establishment of critical limits for each critical control point identified in the hazard analysis. The Department of Health Services may also establish operating limits for any critical control point that is not easily controlled at the critical limit.

(4) Establishment of an appropriate level of monitoring for each critical control point identified in the shoreline and watershed survey and in accordance with minimum monitoring requirements for growing areas as required in Section _____.

(5) Establishment of the corrective action(s) to be taken when a critical limit is exceeded. The intent of the corrective action(s) shall be to regain control of the critical control point prior to restoration of harvesting and shall identify any product that was harvested during the period of time that the critical limit was

exceeded and determine its disposition. The conditions under which harvesting may be resumed shall be defined.

(6) Verification procedures shall be determined that include, but are not limited to, the following:

(A) Validation of the existing or proposed growing area hazard analysis and critical control point procedures plan, to be conducted annually as required in Section ____.

(B) Verification of critical control points that may include targeted sampling and a record review of all corrective actions.

(C) Verification of the entire hazard analysis and critical control point procedures system, in accordance with minimum system verification requirements of Section ____.

(7) Analysis of all bacteriological data in accordance with Section ____.

(8) Analysis of all other chemical, physical, and microbiological data that are pertinent to the hazard analysis and growing area classification.

(9) A determination of the appropriate growing area classification in accordance with Section ____.

(10) Approval of a record-keeping system that will accurately document the hazard analysis and critical control point procedures system, including the existing or proposed growing area hazard analysis and critical control point procedures plan, critical control point monitoring, corrective actions, and verification procedures.

(b) A report shall be prepared containing all of the hazard analysis and critical control point procedures findings. The report shall be distributed to all interested persons including, but not limited to, the applicant, grower, or harvester, the Department of Health Services, and other federal, state, or local agencies that have the responsibility to protect the public health and minimize or eliminate pollution sources identified in the sanitary survey.

(c) The hazard analysis and critical control point procedures shall be valid for a period of twelve (12) years, unless updated through subsequent verification reports. The hazard analysis and critical control point procedures shall be updated through the annual and triennial verification reports in accordance with Section ____ to validate that the current classification is correct, that all requirements pertaining to the current classification have been met, and that environmental conditions relative to growing area hazards are unchanged.

Section 7715.13 Hazard Analysis - Sanitary Survey Requirements.

(a) A sanitary survey, including a shoreline and watershed survey, shall be conducted as part of the hazard analysis of an existing or proposed growing area, and identify all potential biological, chemical, and physical hazards that may impact the existing or proposed growing area.

(b) The shoreline and watershed survey for an existing or proposed growing area shall contain, but not be limited to, the following:

(1) Identification of all potential biological, chemical, and physical hazards within the existing or proposed growing area, along the shoreline in the vicinity of

the existing or proposed growing area, and throughout the immediate watershed of the existing or proposed growing area.

(2) Identification or estimation of the possible sources of pollution related to all potential biological, chemical, and physical hazards, including but not limited to, the following possible sources:

(A) Community, municipal, or other systems for treatment of sewage or other wastes.

(B) Individual sewage treatment systems such as septic systems.

(C) Portable sewage holding facilities.

(D) Domestic animals.

(E) Wild animals.

(F) Resident and migrating bird populations.

(G) Industrial processing facilities and discharges.

(H) Biotoxins and toxigenic phytoplankton.

(I) Recreational or commercial boating activity.

(3) Determination of the significance of each of the identified pollution hazards relative to the potential risk to water and shellfish quality in the existing or proposed growing area. The determination of risk shall be based on, but not limited to, the following:

(A) A survey of water and shellfish quality in the existing or proposed growing area in accordance with Section _____. Representative samples must be collected under adverse pollution conditions to determine the impact from all identified potential hazards.

(B) A survey of water quality near potential hazards that may affect the existing or proposed growing area, as identified in the shoreline survey and watershed survey in accordance with Section _____. Representative samples must be collected under adverse pollution conditions to determine the impact from all identified potential sources of contamination.

(C) An evaluation of the impact of any meteorological, hydrodynamic, and geographic characteristics, such as rainfall, on the potential hazards to water and shellfish quality in the existing or proposed growing area.

(D) The Department of Health Services' experience and data from sanitary surveys and growing area hazard analyses throughout the state.

(E) Any available epidemiological data and other information in the technical literature.

(4) An evaluation shall be made of all existing preventive measures that exist to eliminate or prevent a potential hazard to water and shellfish quality in the existing or proposed growing area, or to reduce the hazard to an acceptable level. This evaluation shall be based on, but not limited to, the following:

(A) Information provided by the agency or individual that is responsible for the prevention and control of each identified potential hazard to the existing or proposed growing area.

(B) Water and shellfish quality data from the existing or proposed growing area and watershed.

(C) Any other relevant valid data.

(5) A determination shall be made of other potential preventive measures that could eliminate or prevent a potential hazard to water and shellfish quality in the existing or proposed growing area, or reduce the hazard to an acceptable level.

(6) The finalized hazard analysis, based on the sanitary survey, shall be incorporated into the hazard analysis and critical control point procedures report in accordance with Section ____.

Section 7715.14 Hazard Analysis - Sampling Plan.

(a) Upon initiating a hazard analysis, the applicant, grower, or harvester shall develop a sampling plan, which must be approved by the Department of Health Services, that contains their requirements and responsibilities in conducting, developing, and completing a hazard analysis and critical control point procedures.

(b) The applicant, grower, or harvester shall enter into a sampling plan agreement for the purpose of generating data needed to support the hazard analysis of the existing or proposed growing area.

(c) The applicant, grower, or harvester shall provide documentation to the Department of Health Services of personnel trained to properly collect, store, and transport water and shellfish samples.

(1) The Department of Health Services and the applicant, grower, or harvester shall maintain a list of all trained personnel who may conduct water and shellfish sampling on behalf of the applicant, grower, or harvester.

(2) The Department of Health Services may remove any person from the list of approved samplers if it has documented concerns regarding their ability to follow the requirements of the sampling plan agreement.

(d) Water and shellfish quality monitoring by the applicant, grower, or harvester will be conducted only by persons designated by the applicant who have been trained and field checked on the procedures outlined in the sampling plan agreement.

(e) The sampling plan shall contain a list and description of all sampling stations and the environmental conditions under which samples are to be collected.

(f) The sampling plan agreement does not prevent the Department of Health Services, or any agency assisting the Department of Health Services, from engaging in additional sampling or any other activities pertaining to sanitation of shellfish.

(g) The applicant, grower, or harvester shall be responsible for the collection, transportation, and analysis, and all associated costs, of all samples necessary for classification and monitoring of the existing or proposed shellfish growing area.

(1) The applicant, grower, or harvester shall provide their sampling personnel with all equipment and supplies needed for sample collection, preservation, and transportation to the laboratory. A list of equipment and supplies shall be included in the sampling plan.

(2) The applicant, grower, or harvester shall take and maintain adequate field notes to ensure that all aspects of sample collection conform to the requirements of the sampling plan.

(3) The applicant, grower, or harvester shall measure water temperature and record this information on the field sheet for each sampling station.

(4) The applicant, grower, or harvester shall measure water salinity and record this information on the field sheet for each sampling station. The applicant, grower, or harvester may have the laboratory responsible for sample analysis to measure and record water salinity if these measurements cannot be performed by the applicant, grower, or harvester.

(5) The applicant, grower, or harvester shall record all environmental information pertinent to sample collection including, but not limited to, tidal stage and direction, weather conditions, and water conditions.

(6) The applicant, grower, or harvester shall submit a copy of the field sheet to the Department of Health Services within 24 hours of sample collection.

(h) The applicant, grower, or harvester shall be responsible for securing the services of a laboratory certified by the State of California for conducting the required analyses. The applicant, grower, or harvester shall instruct the laboratory to transmit a report of all analytical results directly to the Department of Health Services as soon as the analyses are completed.

(i) The applicant, grower, or harvester shall keep all records pertaining to the field collection of samples and the subsequent laboratory analytical results for a period of three (3) years.

(j) The Department of Health Services may revise the sampling plan at any time as a result of changing conditions or new information. The revised sampling plan shall be subject to the same conditions described in this section.

Section 7715.15 Verification of Hazard Analysis and Critical Control Point Procedures.

The hazard analysis and critical control point procedures shall be verified to ensure that adequate control of hazards is maintained and that the hazard analysis and critical control point procedures plan is being followed. Verification of the hazard analysis and critical control point procedures for existing or proposed growing areas shall consist of, but not be limited to, the following:

(a) Validation of the existing or proposed growing area hazard analysis and critical control point procedures.

(b) Verification of all critical control points based on:

(1) Targeted sampling of the hazard being controlled.

(2) An audit of records pertaining to corrective actions following a deviation from a critical limit.

(c) Annual verification of the hazard analysis. The annual verification report shall include:

(1) A review of the cooperation of all involved parties to the hazard analysis and critical control point procedures plan if the existing or proposed growing area is in a conditional classification. This review shall include but not be limited to:

- (A) Cooperation of all involved federal, state, and local agencies.
- (B) Compliance of the applicant, grower, or harvester with the conditions of any self-monitoring agreements developed between them and the Department of Health Services.
- (C) Compliance of the applicant, grower, or harvester with the requirements of the Department of Health Services' marine biotoxin monitoring program.
- (D) Compliance of the applicant, grower, or harvester with all elements of the hazard analysis and critical control point procedures plan.
- (E) Compliance of the applicant, grower, or harvester with any other agreements developed between them and the Department of Health Services.
- (2) Documentation of any changes to known hazards to the existing or proposed growing area.
- (3) Documentation of any new or suspected hazards to the existing or proposed growing area.
- (4) A review of available inspection reports and targeted samples collected from pollution sources.
- (5) A review of available performance standards for discharges that may impact the existing or proposed growing area.
- (6) A review of at least the past year's water quality sample results in accordance with the requirements for bacteriological standards and sample collection as required in Section ____.
- (7) An analysis of the bacteriological data in accordance with the requirements of Section ____.
- (8) Verification of the growing area classification relative to minimum data requirements, critical limits, and other requirements in accordance with Section ____.
- (9) A determination that the existing or proposed growing area is either meeting or failing its current classification requirements.
- (d) If the annual verification process, or any similar verification process conducted at any time, determines that the existing or proposed growing area fails to meet the minimum standards for its current classification, or if an applicant, grower, or harvester is found to be in noncompliance with any of the elements in subdivision (c)(1) of this section, the Department of Health Services shall take any of the following actions:
 - (1) If the existing or proposed growing area is in a conditional classification, and if the reasons for the classification failure are known, predictable, and not so complex as to preclude a reasonable management approach, the existing hazard analysis and critical control point procedures plan shall be modified immediately to mitigate the impact.
 - (A) Mitigation measures may include the adjustment of an existing critical limit or establishment of a new critical control point with a recommended critical limit or operating limit, or a realignment of the growing area boundary so as to exclude the impacted area from the classified area.
 - (B) A verification step shall be required to determine the ability of any mitigation measure to permit the growing area to once again meet the minimum standards for its current classification.

- (2) Immediately close the growing area.
- (3) Close the growing area until the applicant, grower, or harvester demonstrates the ability to comply with all of the elements in subdivision (c)(1) of this section and with any other requirements contained in this Chapter.
- (4) Reclassify the growing area.

Section 7715.50 Biotoxin Hazard Analysis and Critical Control Point Procedures.

(a) A biotoxin hazard analysis and critical control point procedures plan shall be prepared for all shellfish growing areas that are potentially affected by biotoxins.

(b) The biotoxin hazard analysis shall include, but not be limited to, the following:

- (1) Identification of each known or potential biotoxin that may impact a shellfish growing area.
- (2) Determination of the significance of each identified biotoxin relative to the potential public health risk to consumers.
- (3) Evaluation of all existing preventive measures for eliminating or preventing a potential health hazard to consumers, or for reducing the hazard to an acceptable level.
- (4) Determination of other potential preventive measures for eliminating or preventing a potential health hazard to consumers, or for reducing the hazard to an acceptable level.

(c) The biotoxin hazard analysis and critical control point procedures plan for shellfish growing areas potentially affected by biotoxins shall contain the following:

- (1) Results of the biotoxin hazard analysis.
- (2) Establishment of critical control points, based on existing and potential preventive measures identified in the biotoxin hazard analysis.
- (3) Establishment of critical limits for each critical control point in accordance with Section ____.
- (4) Establishment of the appropriate level of monitoring for each critical control point identified in the hazard analysis and in accordance with Section ____.
- (5) Establishment of corrective actions to be taken when a critical limit is exceeded.
- (6) Verification procedures for the biotoxin hazard analysis and critical control point procedures.
- (7) Documentation of any standard operating procedures implemented by the applicant, grower, or harvester, and approved by the Department of Health Services, for site-specific management of marine biotoxins to allow harvesting in designated parts of a growing area while other parts of the growing area are placed in the closed status. The standard operating procedures document shall include descriptions for the monitoring of control points and critical control points, and for corrective actions to be taken in the event a critical limit is exceeded. Such controlled harvesting shall be conducted with strict assurances of safety, such as by batch release of shellfish lots only after representative samples of

each lot are tested and found to be below the critical limits specified in this section.

(8) Establishment of a record-keeping system that will accurately document implementation of and compliance with the biotoxin hazard analysis and critical control point procedures plan, including critical control point monitoring, corrective actions, and verification procedures.

Section 7715.51 Verification of Biotoxin Hazard Analysis and Critical Control Point Procedures.

Verification of the biotoxin hazard analysis and critical control point procedures shall include, but not be limited to, the following:

- (a) Validation of the performance of each certified shellfish grower with respect to the requirements of the biotoxin hazard analysis and critical control point procedures. This validation should be conducted annually in conjunction with the growing area hazard analysis and critical control point procedures plan verification as required in Section ____.
- (b) Verification of critical control points for each biotoxin of concern.
- (c) A record review of all corrective actions taken.
- (d) Verification of the entire biotoxin hazard analysis and critical control point procedures system.

Section 7715.52 Biotoxin Critical Control Limits.

The critical limits for control of biotoxins shall be established by the Department of Health Services in accordance with, but not limited to, the following:

- (a) Paralytic shellfish poisoning toxins shall not be equal to or exceed 80 micrograms per 100 grams of shellfish tissue.
- (b) Neurotoxic shellfish poisoning prevention shall be based on:
 - (1) Finding any detectable neurotoxic shellfish poisoning toxin in shellfish meats, or
 - (2) Cell counts for the causative organism *Gymnodinium breve* in the water column shall not exceed 5,000 per liter.
- (c) Domoic acid shall not be equal to or exceed 20 micrograms per gram of shellfish tissue.
- (d) For any biotoxin-producing organism for which critical limits have not been established, operational limits based on either estimates of cell densities in the water column or biotoxin concentrations in shellfish tissue may be used by the Department of Health Services as the criteria for prohibiting the harvest of shellstock.
- (e) When sufficient data exist to establish species-specific critical limits, the closed status for harvesting may be applied on a species-specific basis.

Section 7715.53 Monitoring of Biotoxin Critical Control Limits and Operational Controls.

(a) Monitoring of biotoxin critical control limits shall be based on, but not be limited to, the following:

(1) The analysis of representative samples of shellfish that shall be collected during all harvest periods. Samples shall be collected from indicator stations at intervals determined by the Department of Health Services and assayed for the presence of toxins.

(2) The level and type of control point and critical control point monitoring employed shall provide an early warning system for the detection of toxigenic phytoplankton blooms or biotoxin concentrations in shellfish tissue in accordance with Section ____.

(3) The level and type of control point and critical control point monitoring employed shall provide a reliable estimate of current risk for each biotoxin of concern.

(4) The frequency of control point and critical control point monitoring employed shall be sufficient to provide a reliable estimate of the trend in toxicity for the species of concern.

(b) When the level of biotoxin present in shellfish tissue has or will likely exceed the critical limit and therefore represents a significant health risk, a growing area shall be placed in the closed status for the taking of shellstock. The growing area shall remain in the closed status until the appropriate corrective actions have been taken and the level of biotoxin is below the critical limit in accordance with Section ____.

(c) Corrective actions taken in response to elevated levels of a biotoxin shall:

(1) Regain control of the critical control point prior to restoration of harvesting.

(2) Identify any product that was harvested during the period of time that the critical limit was exceeded and determine its disposition.

(3) Ensure that harvesting of contaminated species is prevented.

(4) Provide for product recall.

(d) The closed growing area may not be reopened unless the following criteria have been met:

(1) Toxin content of the shellfish in the growing area has stabilized below the critical limit established for closing the area.

(2) The Department of Health Services has determined that toxin levels in the shellfish from adjacent areas are demonstrating a reliable pattern of decline.

Section 7715.54 Biotoxins No Affect on Shellfish Growing Area Classification.

The presence of biotoxins shall not affect the classification of the shellfish growing area as determined by criteria in Article 4, except that the Department of Health Services shall classify as Prohibited any areas where shellfish are so highly or frequently affected by biotoxins that the situation cannot be safely managed. The Conditionally Approved classification may be used for growing areas affected by biotoxins when, in the judgment of the Department of Health Services, the growing areas can be reasonably managed.

Article 4. Shellfish ~~Beds~~ Growing Area Classifications and Operational Requirements

Section 7716.01 Classification – Limitations on Harvesting Activities

- a) A grower or harvester may harvest shellfish for direct marketing from an Approved growing area as defined in Section 112155 of the Health and Safety Code and that meets the criteria for an Approved classification in accordance with Section ____.
- b) Except under certain conditions described in a hazard analysis and critical control point procedures plan, a grower or harvester may harvest shellfish for direct marketing from a Conditionally Approved growing area as defined in Section 112155 of the Health and Safety Code and that meets the criteria for a Conditionally Approved classification in accordance with Section ____.
- c) A grower or harvester may harvest shellfish for direct marketing from a Restricted growing area as defined in Section 112155 of the Health and Safety Code and that meets the criteria for a Restricted classification in accordance with Section ____ only if the shellfish, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.
- d) Except under certain conditions described in a hazard analysis and critical control point procedures plan, a grower or harvester may harvest shellfish for direct marketing from a Conditionally Restricted growing area as defined in Section ____ and that meets the criteria for a Conditionally Restricted classification in accordance with Section ____ only if the shellfish, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.
- e) Except for gathering of seed for aquaculture, no shellfish from a Prohibited area as defined in Section 112155 of the Health and Safety Code and that meets the criteria for a Prohibited area may be harvested for any purpose.

Section 7716.10 Classification of Shellfish Growing Areas.

- (a) All growing areas that do not have a current hazard analysis shall be classified as Prohibited.
- (b) A growing area with a point source hazard such as a sewage treatment plant outfall or other outfall of public health significance within or adjacent to the growing area shall have an area in the Prohibited classification established adjacent to the outfall in accordance with Section ____.
- (c) A growing area shall either be placed in the closed status or reclassified as Prohibited if a pollution hazard occurs that is not adequately addressed in the current hazard analysis as required in Article 3.
- (d) A growing area with a current hazard analysis as required in Article 3 may be classified as Approved, Conditionally Approved, Restricted, Conditionally Restricted, or Prohibited, subject to the provisions of this Article and not excluding any other provision in this Chapter.

(1) The boundaries of each classified growing area shall be delineated on charts, provided by the applicant, grower, or harvester that are of sufficient scale and detail so as to adequately describe the perimeter. This information shall include accurate coordinates for the latitude and longitude of all bounding corners of the growing area.

(2) Any change in growing area classification shall be supported by a current hazard analysis and documented in an annual or triennial verification report in accordance with the provisions of this Chapter.

(A) The verification report shall be distributed to the affected applicant, grower, or harvester, the Department of Health Services, and other federal, state, and local agencies that have the responsibility to protect the public health and minimize or eliminate pollution hazards to the growing area.

(B) A 30-day review and comment period shall precede the reclassification.

Section 7716.11 Status of Growing Area - Not Same as Classification of Growing Area.

The status of a growing area is separate and distinct from its classification, and may be either open or closed for the harvesting of shellstock.

(a) Except for an area in the Prohibited classification, any correctly classified growing area is normally open for the purposes of harvesting shellstock, in accordance with the provisions of this Chapter.

(b) A growing area may be closed to the harvesting of shellfish in accordance with, but not limited to, any of the provisions of this Chapter, including:

(1) The Department of Health Services finds that shellfish harvested from the growing area are or may be unsafe or unfit for human consumption due to a temporary and unusual pollution event or environmental condition, and declares the area or facility to be a closed area pursuant to Section 112160 of the Health and Safety Code.

(2) A growing area temporarily closed shall be reopened only when data show all of the requirements of this Chapter have been met for the current classification, and the Department of Health Services has determined that a public health threat does not exist.

(3) A growing area temporarily closed shall be reopened when the conditions of this Chapter are met and include, but are not limited to, the following:

(A) The emergency situation or condition has abated or been remediated.

(B) Sufficient time has elapsed to allow the shellstock to reduce to acceptable levels of pathogens.

(C) Sufficient time has elapsed to allow the shellstock to reduce to acceptable levels of poisonous or deleterious substances.

(D) The requirements for biotoxin control are met.

(E) The requirements for the growing area hazard analysis and critical control point procedures plan as established in this Chapter are met.

(c) A growing area shall be immediately closed in the event of a known release of sewage into waters adjacent to the growing area. Water samples from the

growing area shall be immediately obtained to assess the initial extent of contamination in the growing area. The growing area shall remain closed until 1) subsequent water sample results demonstrate that fecal coliform concentrations are below critical limits for the growing area and 2) the Department of Health Services has determined that a public health threat does not exist.

Section 7716.12 Bacteriological Monitoring in Shellfish Growing Areas.

- (a) Fecal coliform shall be used as the bacteriological indicator for comparison with critical limits for growing areas.
- (b) The number and location of sampling stations shall be adequate to effectively evaluate all hazards to the growing area.
- (c) The following minimum sampling requirements shall apply for classification of all growing areas except those classified as Prohibited. Samples must be taken under various environmental conditions whereby adverse conditions may be determined.

(1) A growing area that is subjected to hazards that impact water or shellfish quality shall require a minimum of 30 samples from each station. Additional samples may be required if the minimum number of samples do not accurately assess the bacteriological quality of the growing area.

(2) A growing area that is not subjected to hazards that impact water or shellfish quality, and that does not utilize the systematic random sampling strategy, shall require a minimum of 15 samples from each station. Additional samples may be required if the minimum number of samples do not accurately assess the bacteriological quality of the proposed growing area.

Section 7716.13 Bacteriological Monitoring for Verification of Growing Area Classifications.

- (a) Bacteriological monitoring for the purpose of verifying the hazard analysis and critical control point procedures, and therefore the growing area classification, shall be based on either the adverse condition sampling strategy or the systematic random sampling strategy. The appropriate strategy shall be applied according to the following conditions:

(1) Approved and Conditionally Approved growing areas potentially impacted by point source hazards: Bacteriological monitoring for classification verification under this condition must be conducted in accordance with Section _____.

(2) Approved and Conditionally Approved growing areas potentially impacted by non-point source hazards and utilizing the adverse pollution condition sampling strategy: Bacteriological monitoring for classification verification under this condition must be conducted in accordance with Section _____.

(3) Approved and Conditionally Approved growing areas potentially impacted by non-point source hazards and utilizing the systematic random

sampling strategy: Bacteriological monitoring for classification verification under this condition must be conducted in accordance with Section ____.

(4) Restricted and Conditionally Restricted growing areas impacted by point source hazards and used as a shellstock source for shellstock depuration or relaying: Bacteriological monitoring for classification verification under this condition must be conducted in accordance with Section ____.

(5) Restricted and Conditionally Restricted growing areas impacted by non-point source hazards and used as shellstock source for shellstock depuration or relaying: Bacteriological monitoring for classification verification under this condition must be conducted in accordance with Section ____.

(b) Adverse condition sampling shall target the events associated with known or potential hazards to growing area water and shellfish quality. If the current hazard analysis has documented the presence of non-point source hazards, sample station location within the growing area shall be adjacent to actual or potential hazards.

(c) Systematic random sampling strategy shall not be applied to a growing area that is impacted by point source hazards to water and shellfish quality.

(d) Systematic random sampling shall conform to the following criteria, in addition to any other requirements in this Chapter:

(1) Sample station locations are adequate to produce the data to effectively evaluate all non-point source hazards.

(2) Sample collection is scheduled sufficiently far in advance to ensure random collection with respect to environmental conditions.

(A) The schedule for systematic random sampling for the growing area shall be approved by the Department of Health Services.

(B) If a scheduled sample collection occurs either when environmental conditions are believed to be hazardous to the safety of the individuals assigned to collect samples, or when the growing area is closed to harvest, the applicant, grower, or harvester shall notify the Department of Health Services immediately. The applicant, grower, or harvester shall determine a new sample collection date which shall be scheduled as soon as the limiting condition permits and which must be approved by the Department of Health Services.

Section 7716.14 Approved Shellfish Growing Area Classification.

A growing area may be classified as Approved when the following criteria are met:

(a) A current hazard analysis exists that meets the requirements of Section ____ for the growing area, and the hazard analysis has determined that:

(1) The shellfish in the growing area are safe for direct marketing for human consumption.

(2) The growing area is not subject to contamination from human or animal fecal matter at levels that presents an actual or potential public health hazard.

(3) The growing area is not contaminated with pathogenic organisms, poisonous or deleterious substances, marine biotoxins, or fecal coliform concentrations exceeding the critical limits for the Approved classification.

- (4) The water and shellfish quality in the growing area meet the critical limits for an Approved classification in accordance with Section ____.
- (b) The classification of an Approved growing area shall be verified at least once each year in accordance with the hazard analysis and critical control points procedure verification process as required in Section ____.
- (c) All other provisions of this Chapter relating to growing area classification are met.

Section 7716.15 Conditionally Approved Shellfish Growing Area Classification.

A growing area may be classified as Conditionally Approved when the following criteria are met:

- (a) A hazard analysis and critical control point procedures report has been prepared in accordance with Section ____.
 - (1) The hazard analysis and critical control point procedures report has been distributed to the applicant, grower, or harvester, the Department of Health Services, and other federal, state, and local agencies that have the responsibility to protect the public health and minimize or eliminate pollution hazards to the growing area.
 - (2) A 30-day review and comment period has been completed.
- (b) A current hazard analysis exists that meets the requirements of Section ____ for the growing area, and the hazard analysis has determined that:
 - (1) The growing area will be in the open status in the Conditionally Approved classification for a minimum of six months of the calendar year. The critical limit for controlling each hazard shall be known, predictable and measurable, and shall not be so complex as to preclude a reasonable management approach.
 - (2) Each potential hazard to water and shellfish quality in the growing area has been evaluated in accordance with Section ____.
 - (3) Microbiological measures of water and shellfish quality correlate with environmental conditions or other factors affecting the distribution of pollutants into the growing area from known or potential hazards.
- (c) A written growing area hazard analysis and critical control point procedures plan shall be developed for each Conditionally Approved growing area. The growing area hazard analysis and critical control point procedures plan shall contain all information necessary for the proper management of the Conditionally Approved growing area.
- (d) A Conditionally Approved growing area that has a hazard analysis and critical control point procedures plan based on wastewater treatment plant function shall establish the critical control points for plant performance, and their corresponding critical limits, based on, but not limited to, the following:
 - (1) Peak effluent flow, average flow, and infiltration flow.
 - (2) Microbiological quality of the effluent.
 - (3) Physical and chemical quality of the effluent.
 - (4) Conditions which cause plant failure.
 - (5) Records indicating frequency of plant or collection system bypasses.

(6) Design, construction, and maintenance features that minimize mechanical failure or overloading.

(7) Provisions for monitoring and inspecting the wastewater treatment plant.

(8) Establishment of an area in the Prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section ____.

(e) A Conditionally Approved growing area that has a hazard analysis and critical control point procedures plan based on pollution hazards other than a wastewater treatment plant shall establish the critical control points, and their corresponding critical limits, in accordance with Section _____. The critical or operational limits shall reliably control the hazard, ensuring that water and shellfish quality in the growing area meet the bacteriological critical limits or any other critical limits established by the Department of Health Services for the growing area.

(f) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area shall establish the corrective actions necessary to regain control of any hazard or issue of noncompliance that causes the growing area to be placed in the closed status. These corrective actions shall be based on, but not limited to, the following:

(1) All critical limits or operational limits established in the plan are fully met.

(2) The applicant, grower, or harvester is in compliance with the provisions of the hazard analysis and critical control point procedures plan for their growing area.

(3) Sufficient time has elapsed to allow the water and shellfish quality in the growing area to at least return to the critical limits established in Section ____.

(4) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels as measured by the fecal coliform group of indicator organisms in the water and shellstock.

(5) Additional data from other bacterial or viral indicators of the presence of pathogens or the levels of the actual pathogen, may be used in conjunction with the fecal coliform data.

(6) Shellstock feeding activity is sufficient to achieve adequate fecal coliform reduction.

(g) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area shall establish the corrective actions necessary to regain control of any marine biotoxin hazard, or any issue of noncompliance relating to marine biotoxin monitoring, that causes the growing area to be placed in the closed status.

(h) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area shall establish the procedures for immediate notification to the Department of Health Services by any person or agency that is responsible for monitoring the critical limit of a known or potential hazard when the limit is exceeded.

(i) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area shall establish the procedures necessary to

immediately place the growing area in the closed status within 24 hours when the criteria established in the hazard analysis and critical control point procedures plan are not met.

(j) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area may contain a sanitation standard operating procedure developed by the applicant, grower, or harvester to document a specific procedure or process that requires control to prevent unacceptable levels of fecal coliform in their growing area or shellstock.

(k) The classification of a Conditionally Approved growing area shall be verified at least once each year in accordance with the hazard analysis and critical control point procedures verification process as required in Section ____.

(l) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area shall require monthly water samples when the growing area is in the open status of its Conditional classification in accordance with Section ____, with the following exceptions:

(1) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(2) If the hazard analysis and critical control point procedures plan for a Conditionally Approved growing area is based entirely on the absence of pollution from marinas at certain times of the year, the Department of Health Services may determine that monthly samples are not required when the growing area is in the open status. If the Department of Health Services so decides, the requirement shall be that at least three of the water samples collected to satisfy the bacteriological monitoring requirements of Section ____ are collected when the growing area is in the open status.

(m) The hazard analysis and critical control point procedures plan for a Conditionally Approved growing area shall be developed by the applicant, grower, or harvester, and approved by the Department of Health Services, in coordination with the following:

(1) The local shellfish industry.

(2) The individuals responsible for the operation of any wastewater treatment plants involved.

(3) Any local or state agencies involved in aquaculture, water quality, use permits for a proposed or existing aquaculture site, or any other activity that bears on the management of the growing area.

Section 7716.16 Critical Limits for Fecal Coliform for Approved and Conditionally Approved Shellfish Growing Areas.

Approved or Conditionally Approved growing areas shall meet the following critical limits for fecal coliform:

(a) The geometric mean of the data for water samples from each growing area station shall not exceed a Most Probable Number of 14 per 100 milliliters; and

(1) Not more than 10 percent of the water samples collected under adverse pollution conditions from each growing area station shall exceed a Most Probable Number of 43 per 100 milliliters for a 5-tube decimal dilution test; or

(2) The estimated 90th percentile of the water samples collected under the systematic random sampling strategy shall not exceed a Most Probable Number of 43 per 100 milliliters for a 5-tube decimal dilution test.

(b) The geometric mean of the data for samples of marketable shellfish from each growing area station shall not exceed a Most Probable Number of 230 per 100 grams, and not more than 10 percent of the data for samples of marketable shellfish from each growing area station shall exceed a Most Probable Number of 700 per 100 grams for a 5-tube decimal dilution test.

Section 7716.17 Bacteriological Monitoring for Verification of Growing Area Classifications - Approved and Conditionally Approved Growing Areas Potentially Impacted by Point Source Hazards.

Bacteriological monitoring for verification of Approved and Conditionally Approved growing areas potentially impacted by point source hazards shall meet the following criteria, in addition to any other requirements in this Chapter:

(a) Sample station location within the growing area shall be adjacent to actual or potential hazards.

(b) The following minimum requirements for annual sample collection shall apply:

(1) Approved growing areas shall have a minimum of five (5) samples collected annually under adverse pollution conditions from each sample station in the growing area when the area is open for harvest.

(2) Conditionally Approved growing areas shall have a minimum of one (1) sample per month collected under adverse pollution conditions from each sample station in the growing area when the area is open for harvest.

(3) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(c) The following minimum data requirements for verification of the growing area classification shall apply. These data shall be used to calculate the geometric mean and percentage to determine compliance with the bacteriological critical limits.

(1) Verification of an Approved growing area shall be based on a minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station.

(2) Verification of a Conditionally Approved growing area shall be based on a minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station.

(d) The bacteriological water quality of every station in the growing area shall meet the following fecal coliform critical limits:

(1) The geometric mean of the data for water samples from each growing area station shall not exceed a Most Probable Number of 14 per 100 milliliters, and

(2) Not more than 10 percent of the water samples collected under adverse pollution conditions from each growing area station shall exceed a Most Probable Number of 43 per 100 milliliters for a 5-tube decimal dilution test.

(e) Harvestable shellfish must meet bacteriological standards in accordance with Section ____ during open harvest periods.

Section 7716.18 Bacteriological Monitoring for Verification of Growing Area Classifications - Approved and Conditionally Approved Growing Areas Potentially Impacted by Non-point Source Hazards and Utilizing the Adverse Pollution Condition Sampling Strategy.

Bacteriological monitoring for verification of Approved and Conditionally Approved growing areas potentially impacted by non-point source hazards and utilizing the adverse pollution condition sampling strategy shall meet the following criteria, in addition to any other requirements in this Chapter:

(a) The growing area shall be impacted only by randomly occurring, intermittent events.

(b) The growing area shall not be impacted by discharges from sewage treatment facilities or combined sewer overflows.

(c) The minimum requirements for annual sample collection established in Section ____ shall apply.

(d) The minimum data requirements for verification of the growing area classification established in Section ____ shall apply. These data shall be used to calculate the geometric mean and percentage to determine compliance with the bacteriological critical limits.

(e) The bacteriological water quality and shellfish quality of every station in the growing area shall meet the fecal coliform critical limits in accordance with Section ____.

Section 7716.19 Bacteriological Monitoring for Verification of Growing Area Classifications - Approved and Conditionally Approved Growing Areas Potentially Impacted by Non-point Source Hazards and Utilizing the Systematic Random Sampling Strategy.

Bacteriological monitoring for verification of Approved and Conditionally Approved growing areas potentially impacted by non-point source hazards and utilizing the systematic random sampling strategy shall meet the following criteria, in addition to any other requirements in this Chapter:

(a) The following minimum requirements for annual sample collection shall apply:

(1) Approved growing areas shall have a minimum of six (6) random samples collected annually from each sample station in the growing area.

(2) Conditionally Approved growing areas shall have a minimum of one (1) random sample collected per month from each sample station in the growing area when the area is open for harvest.

(b) Verification of the growing area classification shall be based on a minimum of the 30 most recent randomly collected samples from each sample station. These

data shall be used to calculate the geometric mean and 90th percentile to determine compliance with the bacteriological critical limits.

(c) The bacteriological water quality of every station in the growing area shall meet the following fecal coliform critical limits:

(1) The geometric mean of the data for water samples from each growing area station shall not exceed a Most Probable Number of 14 per 100 milliliters, and

(2) The estimated 90th percentile shall not exceed a Most Probable Number of 43 per 100 milliliters for a 5-tube decimal dilution test.

(d) Harvestable shellfish must meet bacteriological standards in accordance with Section ____ during open harvest periods.

Section 7716.20 Restricted Shellfish Growing Area Classification.

A growing area may be classified as Restricted when a current hazard analysis determines that:

(a) Pollution exists such that water and shellfish quality in the growing area do not meet the critical limits for an Approved area for a reasonable period of time.

(b) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying or depuration.

(c) The applicant, grower, or harvester has been granted either a Shellstock Relaying Certificate or a Depuration Processor Certificate by the Department of Health Services in accordance with Section ____ and Section ____, and has satisfied any other requirements in this Chapter.

(d) Water and shellfish quality in the growing area shall meet the bacteriological critical limits in accordance with Section ____.

Section 7716.21 Conditionally Restricted Shellfish Growing Area Classification.

A growing area may be classified as Conditionally Restricted when the conditions specified in Section ____ have been met and:

(a) A current hazard analysis determines that water and shellfish quality meet the critical limits for a Restricted area when the area is in the open status.

(b) The growing area is in the open status for a reasonable period of time.

(c) A hazard analysis and critical control point procedures plan has been developed in accordance with the relevant provisions of Section ____.

(d) The applicant, grower, or harvester has been granted either a Shellstock Relaying Certificate or a Depuration Processor Certificate by the Department of Health Services in accordance with Section ____ and Section ____, and has satisfied any other requirements in this Chapter.

(e) The hazard analysis and critical control point procedures plan for the Conditionally Restricted growing area shall designate whether the harvested shellstock are to be relayed or depurated.

(1) If the grower has specified the use of shellstock from the Conditionally Restricted area for relaying to an Approved growing area, the grower must obtain

a Shellstock Relaying Certificate from the Department of Health Services in accordance with Section ____ and Section ____, and must have satisfied any other requirements in this chapter.

(2) If the grower has specified the use of shellstock from the Conditionally Restricted area for depuration, the grower must be in possession of a Depuration Processor Certificate in accordance with the provisions of Chapter 12.

Section 7716.22 Critical Limits for Fecal Coliform for Restricted and Conditionally Restricted Shellfish Growing Areas.

Restricted and Conditionally Restricted growing areas shall meet the following critical limits for fecal coliform:

(a) The geometric mean of the data for water samples from each growing area station shall not exceed a Most Probable Number of 88 per 100 milliliters; and

(1) Not more than 10 percent of the water samples collected under adverse pollution conditions from each growing area station shall exceed a Most Probable Number of 260 MPN per 100 milliliters for a 5-tube decimal dilution test; or

(2) The estimated 90th percentile of the water samples collected under the systematic random sampling strategy shall not exceed a Most Probable Number of 260 per 100 milliliters for a 5-tube decimal dilution test.

Section 7716.23 Bacteriological Monitoring for Verification of Growing Area Classifications - Restricted and Conditionally Restricted Growing Areas Impacted by Point Source Hazards and Used as a Shellstock Source for Shellstock Depuration or Relaying.

Bacteriological monitoring for verification of Restricted and Conditionally Restricted growing areas impacted by point source hazards and used as a shellstock source for shellstock depuration or relaying shall meet the following criteria, in addition to any other requirements in this Chapter:

(a) Sample station location within the growing area shall be adjacent to actual or potential hazards.

(b) The following minimum requirements for annual sample collection shall apply:

(1) Restricted growing areas shall have a minimum of five (5) samples collected annually under adverse pollution conditions from each sample station in the growing area when the area is open for harvest.

(2) Conditionally Restricted growing areas shall have a minimum of one (1) sample per month collected under adverse pollution conditions from each sample station in the growing area when the area is open for harvest.

(c) Verification of the growing area classification shall be based on a minimum of the most recent 15 samples collected under adverse pollution conditions from each sampling station. These data shall be used to calculate the geometric mean and percentage to determine compliance with the bacteriological critical limits.

(d) The bacteriological water quality of every station in the growing area shall meet the fecal coliform critical limits in accordance with Section ____.

(e) The Department of Health Services shall establish the critical limits for levels of contaminants in shellstock. These criteria should be based on the effectiveness of the treatment process being applied to the shellstock, namely relaying or depuration, in accordance with Section ____.

Section 7716.24 Bacteriological Monitoring for Verification of Growing Area Classifications - Restricted and Conditionally Restricted Growing Areas Impacted by Non-point Source Hazards and Used as Shellstock Source for Shellstock Depuration or Relaying.

Bacteriological monitoring for verification of Restricted and Conditionally Restricted growing areas impacted by non-point source hazards and used as a shellstock source for shellstock depuration or relaying shall meet the following criteria, in addition to any other requirements in this Chapter:

(a) The growing area shall be impacted only by randomly occurring, intermittent events.

(b) The growing area shall not be impacted by discharges from sewage treatment facilities or combined sewer overflows.

(c) The following minimum requirements for annual sample collection shall apply:

(1) Restricted growing areas shall have a minimum of five (5) samples collected annually under adverse pollution conditions from each sampling station in the growing area when the area is open for harvest.

(2) Conditionally Restricted growing areas shall have a minimum of one (1) sample collected per month under adverse pollution conditions from each sample station in the growing area when the area is open for harvest.

(d) The following minimum data requirements for verification of the growing area classification shall apply:

(1) Under the adverse pollution condition sampling strategy, a minimum of the most recent 15 samples collected from each sampling station shall be used to calculate the geometric mean and percentage to determine compliance with the bacteriological critical limits.

(2) Under a systematic random sampling strategy, a minimum of the 30 most recent randomly collected samples from each sample station shall be used to calculate the geometric mean and 90th percentile to determine compliance with the bacteriological critical limits.

(e) The bacteriological water quality of every station in the growing area shall meet the fecal coliform critical limits in accordance with Section ____.

(f) The Department of Health Services shall establish the critical limits for levels of contaminants in shellstock. These criteria should be based on the effectiveness of the treatment process being applied to the shellstock, namely relaying or depuration, in accordance with Section ____.

Section 7716.25 Areas Classified as Prohibited.

(a) An area may be classified as Prohibited in the absence of a current hazard analysis, or in accordance with any other provision in this Chapter regarding Prohibited areas, or if a current hazard analysis determines that:

(1) The area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance.

(2) Pollution sources may unpredictably contaminate the area.

(3) The area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms.

(4) The concentration of biotoxin in the area is sufficient to cause a public health risk as identified in Section ____.

(5) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.

(6) The shellstock in the area are not safe for human consumption.

(b) An area classified as Prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance. The determination of the size of the area to be classified as Prohibited adjacent to each outfall should include the following minimum criteria:

(1) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological quality of the effluent.

(2) The decay rate of the contaminants of public health significance in the wastewater discharged.

(3) The reduction of bacterial or viral pathogens in the discharged wastewater by dilution, dispersion, and die-off.

(4) The time of waste transport to the area where shellstock may be harvested.

(5) The location of the shellfish resource, classification of adjacent waters and identifiable landmarks or boundaries.

(c) The Prohibited classification is not required for harvest waters within or adjacent to marinas.

(d) Except for the harvest of shellstock for the gathering of seed for aquaculture in accordance with Section ____ or the depletion of the areas classified as Prohibited, the harvest of shellstock from any area classified as Prohibited is not allowed.

Section 7716.26 Classification of Areas Within and Around Marinas.

(a) The area within any marina which is in or adjacent to a shellstock growing area shall be classified as:

(1) Conditionally Approved, or

(2) Conditionally Restricted, or

(3) Prohibited.

(b) For waters adjacent to marina waters, a dilution analysis shall be used to determine if there is any impact by pollution.

(1) The dilution analysis shall be based on the volume of water in the vicinity of the marina.

(2) The dilution analysis shall incorporate the following:

- (A) A slip occupancy rate for the marina.
- (B) An actual or assumed rate of boats which will discharge untreated waste.
- (C) An occupancy per boat rate (i.e., number of persons per boat).
- (D) A fecal coliform discharge rate of 2,000,000,000 fecal coliform per person per day.
- (E) The assumption that the wastes are completely mixed in the volume of water in and around the marina.

(3) If the dilution analysis predicts a theoretical fecal coliform loading greater than a Most Probable Number of 14 per 100 milliliters, the waters adjacent to the marina shall be classified as:

- (A) Conditionally Approved, or
- (B) Restricted, or
- (C) Conditionally Restricted, or
- (D) Prohibited.

(4) If the dilution analysis predicts a theoretical fecal coliform loading less than or equal to a Most Probable Number of 14 per 100 milliliters, the waters adjacent to the marina may be classified as:

- (A) Approved, or
- (B) Conditionally Approved.

(5) If a specific occupancy per boat rate is not determined by investigation in specific areas or sites, a minimum occupancy rate of two persons per boat shall be used.

Section 7716.50 Certified Laboratories and Analytical Methods.

(a) All microbiological, chemical, and physical analyses of shellfish and shellfish growing waters shall be performed by a laboratory certified by the State of California.

(b) Methods for microbiological analysis of shellfish and shellfish growing waters shall be the methods required by the National Shellfish Sanitation Program.

(c) Methods for chemical and physical analysis of shellfish and shellfish growing waters shall be the current American Public Health Association methods for chemical and physical measurements.

(d) Methods for the analysis of biotoxins in shellfish and other seafoods shall be the current American Public Health Association methods for biotoxins.

Article 5. ~~Plants and Operations~~ Shellfish Open Water Aquaculture, Seed Shellstock, Wet Storage, and Shellstock Relaying

Section 7717.10 Shellfish Open Water Aquaculture.

(a) Any person engaged in open water aquaculture for human consumption shall, prior to commencing these activities:

(1) Apply to the Department of Health Services for a Shellfish Growing Area Certificate in accordance with the provisions of Article 2, and

(2) Comply with all requirements regarding the management and classification of shellfish growing areas in accordance with the provisions of Article 3 and Article 4.

(b) Complete and accurate records shall be maintained for at least three (3) years by the applicant, grower, or harvester and shall be made available for inspection by the Department of Health Services or its agents during all reasonable hours. Upon request, these records shall be submitted to the Department of Health Services within seven (7) days. These records shall, at a minimum, include:

(1) Source of shellfish, including seed.

(2) Dates of transplanting of shellstock and seed.

(3) Locations of transplanting of shellstock and seed.

(4) Dates, locations, and quantity of harvest for each shellfish species.

Section 7717.11 Seed Shellstock.

(a) All sources of seed must first be approved by the Department of Health Services or its duly authorized agent before transplanting to certified shellfish growing areas.

(b) The following criteria shall be used to establish the submarket size for each species of shellfish:

(1) A maximum shell length of:

(A) Thirteen millimeters (1/2 inch) for mussels;

(B) Twenty-five millimeters (one inch) for scallops;

(C) Nineteen millimeters (3/4 inch) for Olympia oysters;

(D) Nineteen millimeters (3/4 inch) for Kumamoto oysters

(E) Fifty-one millimeters (two inches) for other oyster species;

(F) Thirty-eight millimeters (one and 1/4 inch) for geoducks; and

(G) Thirteen millimeters (1/2 inch) for other clam species.

(2) All seed shellstock shall require at least six (6) months to reach the minimum market size.

(c) Seed may come from any growing area in any classification, provided that:

(1) The source of the seed is permitted by the Department of Health Services.

(2) Seed from growing areas in the Restricted or Prohibited classification shall not have levels of poisonous or deleterious substances in excess of established standards for those substances.

(3) The source of seed is not within an existing closure zone.

(4) Seed from an area classified as Prohibited shall be cultured for a minimum of six (6) months before marketing for human consumption.

(5) The harvest of seed from an Approved or Conditionally Approved growing area shall follow the provisions of Section ____ regarding wet storage requirements.

(d) Any person engaged in the harvest of seed for transplanting in Approved or Conditionally Approved growing areas shall possess a valid Shellstock Seed Transplanting Certificate issued by the Department of Health Services in accordance with Section ____.

(e) When a Shellstock Seed Transplanting Certificate application has been accepted for filing and the applicant has been notified, the Department of Health Services will determine if a hazard analysis is required for the proposed seed harvest location.

(1) Upon initiating a hazard analysis, the applicant, grower, or harvester shall develop a sampling plan, which must be approved by the Department of Health Services, that contains their requirements and responsibilities in conducting, developing, and completing a hazard analysis and critical control point procedures in accordance with the provisions of Article 3.

(2) When a hazard analysis is required for the proposed seed harvest location, it shall be performed under the guidance of the Department of Health Services and in accordance with the provisions of Article 3.

(3) The hazard analysis of the proposed seed harvest area shall include identification of all potential poisonous and deleterious substances that may impact the area.

(4) The hazard analysis report shall describe the findings of the hazard analysis, including:

(A) A list of known or potential poisonous or deleterious substances that may impact the seed harvest area.

(B) The results of all sample analyses for the known or potential poisonous or deleterious substances.

(C) A comparison of the sample analysis results to current standards or limits associated with each poisonous or deleterious substance.

(f) Prior to any harvesting, a seed harvesting area shall meet the requirements of this Chapter and a Shellstock Seed Transplanting Certificate must have been issued which shall include the following requirements:

(1) Seed shall be harvested during daylight hours only.

(2) The applicant, grower, or harvester shall notify the Department of Health Services in writing 14 days prior to the proposed seed harvest and transplant operation.

(3) The transplant area receiving shellstock seed shall be clearly marked and posted as CLOSED for a period of six (6) months. During this six month closed period, there shall be no aquaculture activities, including culling, sorting and harvesting, within the transplant area.

(g) The following records shall be maintained for each shellstock seed harvesting and transplanting operation, and shall be sent to the Department of Health Services as specified:

(1) Records to be sent to the Department of Health Services within seven (7) days of the completion of the seed harvest and transplant operation:

- (A) Date and location of seed harvest.
- (B) Amount of each species of seed harvested.
- (C) Date and location of transplanting.

(2) Records to be sent to the Department of Health Services at a frequency prescribed by the Department.

- (A) Date, location, species, and lot number of harvested shellstock.
- (B) Number of shellstock harvested for each species, except harvests of clams may be expressed as pounds harvested.
- (C) Identification of buyer.
- (D) The amount purchased.
- (E) The date of purchase.

(h) Hatcheries are exempted from these requirements.

Section 7717.12 Wet Storage.

(a) Any person engaged in the wet storage of shellstock shall possess a valid Wet Storage Certificate issued by the Department of Health Services in accordance with Section ____.

(b) The dealer shall have an operational plan or standard operating procedures approved by the Department of Health Services for the wet storage operation that:

- (1) Describes the source and type of shellstock to be wet stored.
- (2) Describes the exact location where wet storage will occur and the method used to maintain adequate separation between different lots of shellfish. The method employed shall be easily visible and distinguishable from a distance of 500 feet.
- (3) Describes the method in which shellstock shall be held in the wet storage area.
- (4) Describes the record-keeping system employed to adequately track the source, location, movement, and harvest of each lot of shellfish.
- (5) Contains all forms used for record-keeping purposes.
- (6) Meet the requirements of Section ____.

(c) The dealer shall wet store shellstock harvested only from:

- (1) A certified commercial shellfish growing area in the open harvest status and classified as either Approved or Conditionally Approved, or
- (2) A certified depuration facility following successful completion of the depuration process.

(d) Shellstock shall be harvested, identified and shipped to the wet storage operation in accordance with the requirements of Section ____.

(e) Wet storage of depurated product shall occur only within the facility in which it was depurated.

(f) While awaiting placement in a wet storage operation, shellstock shall be protected from physical, chemical or thermal conditions that may compromise the survival, quality or activity of the shellstock during wet storage.

(g) Storage conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

(h) Near shore waters used for wet storage shall meet the requirements for classification as Approved or Conditionally Approved. Areas classified as Conditionally Approved may be used only when in the open status. When an area classified as Conditionally Approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:

(1) Subjected to relaying or depuration prior to human consumption, or

(2) Held in the wet storage site until the area is returned to the open status.

(i) Different lots of shellstock shall not be commingled in wet storage. If more than one lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained and clearly marked.

(j) Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of Section ____.

(k) When wet-stored shellstock that originated from a certified shellfish growing area in accordance with Section ____ is harvested from the wet storage site within 90 days of transfer to that site, the shipping tag shall include the following information:

(1) The full information required on the dealer's tag in accordance with the requirements of Section ____, and

(2) The following statement: THIS PRODUCT IS A PRODUCT OF (NAME OF STATE), WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE), AND WAS GROWN AT (CERTIFIED LEASE DESIGNATION).

(l) When wet-stored shellstock that originated from a certified shellfish growing area in accordance with Section ____ is harvested from the wet storage site after 90 days of transfer to that site, it is considered a product of that wet storage site.

(m) Any dealer who wet stores shellstock from another state and ships the shellstock as a product of the state where the shellstock was wet stored shall be required to:

(1) Have an operational plan or standard operating procedures approved by the Department of Health Services in accordance with Section ____, and

(2) Provide a description on how this labeling change will be employed in assuring that shellstock can be traced to its source, and

(3) Meet the requirements of Section ____.

(n) When the product from wet storage is depurated prior to wet storage, the shellstock shall:

(1) Be packed and labeled according to the requirements of Section ____, and

(2) Meet all other requirements of this Chapter.

(o) The wet storage operator shall keep complete and accurate records as detailed in their operational plan or standard operating procedures to enable a lot of shellstock to be traced back to the wet storage location and to the certified growing area of origin. The records shall be maintained for at least one year.

(p) Each offshore wet storage site or operation shall be evaluated annually for the purpose of certification. The evaluation shall include:

(1) An inspection of the offshore wet storage site, including all boundary markers, structures and floats used in the operation.

(2) An examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock.

(3) A reevaluation of all water and shellfish quality monitoring data for the site, and a review of the current sanitary survey of the near shore storage site, with special consideration for potential intermittent sources of pollution.

(4) A review of the dealer's wet storage records to ensure compliance with the requirements of this Chapter for shellstock lot tracking.

Section 7717.13 Shellstock Relaying.

(a) Any person engaged in the relaying of shellstock intended for sale for human consumption shall possess:

(1) A valid Shellstock Relaying Certificate issued by the Department of Health Services.

(2) A valid Shellfish Growing Area Certificate issued by the Department of Health Services.

(3) Any other required permits, licenses, or permission from other state or local agencies to engage in relaying activities.

(b) Shellstock used in relaying activities shall be harvested from growing areas classified as Approved, Conditionally Approved, Restricted, or Conditionally Restricted.

(c) The level of contamination in the shellstock must be reduced to levels safe for human consumption prior to release from relaying.

(d) The contaminated shellstock shall be held in growing areas classified as Approved or Conditionally Approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens, as measured by the fecal coliform group of indicator organisms, and/or poisonous or deleterious substances that may be present in shellstock.

(e) If shellstock are relayed in containers:

(1) The containers shall be designed and constructed as to allow free flow of water to the shellstock, and located so as to assure contaminant reduction as required in this Chapter.

(2) The shellstock shall be washed and culled prior to placement in the containers.

(f) Species-specific critical limits shall be established for water temperature, salinity and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical limits may be approached.

(g) The effectiveness of species-specific contaminant reduction shall be determined based on a study of the growing area where shellstock will originate and the area where shellstock will be relayed.

(1) A species-specific contaminant reduction study shall include a sampling plan.

(2) Upon completion of the species-specific contaminant reduction study, a report shall be prepared that describes the findings of the study, including:

(A) A list of known or potential poisonous or deleterious substances that may impact the source of shellstock.

(B) The results of all sample analyses.

(C) A comparison of the sample analysis results to current standards or limits associated with the fecal coliform indicator group and with each poisonous or deleterious substance of concern.

(D) A comparison of the bacteriological quality of each shellfish species to the bacteriological quality of the same species already present in the shellstock source area.

(E) A comparison of contaminant levels of poisonous or deleterious substances in shellstock to U.S. Food and Drug Administration tolerance levels.

(h) The time period for contaminant reduction shall be at least 14 consecutive days when environmental conditions are suitable for shellfish feeding and cleansing, unless shorter time periods are demonstrated to be adequate.

(i) When container relaying is used and the Department of Health Services allows a treatment time of less than 14 days, more intensive sampling shall be required and shall at a minimum include:

(1) Product sampling before and after relay.

(2) Monitoring of critical environmental parameters such as temperature and salinity.

(j) The Department of Health Services shall establish the time period during the year when relaying may be conducted.

Section 7717.14 Management of Shellstock Relaying Activities.

(a) Shellstock relaying shall take place during daylight hours only.

(b) The applicant, grower, or harvester shall notify the Department of Health Services in writing 14 days prior to the proposed relay operation.

(c) If shellstock from growing areas classified as Conditionally Approved, Restricted, or Conditionally Restricted are to be relayed across State or national boundaries, an official agreement outlining the procedures to be used shall be developed between the appropriate enforcement agencies in each State or nation prior to issuance of a Shellstock Relaying Certificate.

(d) If a growing area in the Conditionally Approved classification meets the criteria for the Restricted classification when the growing area is in the closed status, the Department of Health Services may permit shellstock to be harvested for relaying during the period the growing area is in the closed status, provided that relaying is addressed in the hazard analysis and critical control point procedures plan for the growing area classified as Conditionally Approved, and all other conditions of this Chapter are met.

(e) Locations designated to receive relayed shellstock within growing areas that are classified as Approved or Conditionally Approved shall:

(1) Be placed in the closed status until the period of treatment is complete and the Department of Health Services returns the area to the open status.

(2) Be marked so that these areas are easily identified by harvesters transporting the relayed shellstock and by the Department of Health Services.

These areas shall:

(A) Be marked prior to the placing of any shellstock.

(B) Remain marked until the Department of Health Services reopens the area and gives written permission to harvest shellstock.

(C) Be adequately separated from the shellstock in adjacent waters to prevent cross-contamination and commingling.

Section 7717.50 Patrol and Monitoring of Shellfish Growing Areas and Operations.

The Department of Health Services may, at any time, on its own or through coordination with other federal, state, or local agencies, monitor shellfish operations and patrol shellfish growing areas to ensure that all shellfish operations, including shellfish aquaculture operations, seed shellstock operations, and shellstock relaying operations, are in compliance with all requirements of this Chapter.

Article 6. Safety of Shellfish and Health of Employees, Records, and Shellfish
Beds

Section 7719 Safety of Shellfish for Human Consumption.

No shellfish shall be sold or distributed for human consumption unless it is safe as an article of food and is free from filth.

Section 7720 Persons Infected With Communicable Diseases.

Persons who are infected with or are carriers of organisms of typhoid fever, dysentery, septic sore throat, hepatitis A or ~~certain~~ any other communicable diseases which might be transmitted through shellfish or who have infected wounds or open lesions on exposed portions of the body shall not be employed in the growing beds or shucking, packing, or repacking plant. If the owner or manager has reason to suspect that any employee has contracted such a communicable disease, he shall immediately exclude said employee from the growing beds or plant.

~~Article 3. Records~~

Section 7725 Record of Operations.

A daily record of shellfish received and shipped shall be kept showing kinds of shellfish, designation of the beds from which derived, name of grower, name of shipper, and name of consignee. These records shall be available for inspection by the ~~State Department of Public Health~~ Department of Health Services or its agents during all reasonable hours. Upon request these records shall be submitted to the ~~State Department of Public Health~~ Department of Health Services.

~~Article 4. Shellfish Beds~~

Section 7730 Cleanliness of Shellfish Growing Areas.

Shellfish beds shall be located in growing areas not adversely affected by sewage, other wastes, or human and recreational activity. All operation of the beds shall be such as not to adversely affect the cleanliness of the growing area.

Section 7731 Boat Sanitation.

All boats, scows, and appurtenances thereto used in the taking of shellfish or used in the transportation of shellfish from the beds to plants or used in the water over the shellfish beds shall be kept in such a state of cleanliness and repair that shellfish growing on the bed and handled and stored

thereon shall not be subject to contamination. Decks, holds, or bins used for storage and/or transporting of shellfish on boats shall not be washed with polluted water. Persons in boats over the shellfish beds shall not discharge human wastes to the waters. Adequate facilities shall be provided for disposal of human wastes from persons working on the shellfish beds.

Section 7732 Shellfish From Uncertified Areas Brought Into Certified Beds.

Shellfish growing in uncertified areas may not be brought into a bed for which a certificate has been issued unless special approval is first granted by the ~~State Department of Public Health~~ Department of Health Services. Such approval shall be in writing and granted only on condition that the method of transplanting and timing of arrival of the shellfish will insure that the transplanted shellfish remain in the approved growing area at least 30 days before harvesting for sale for human consumption. This translating area must be in separate portions of the bed and one in which no other shellfish are held.

Section 7733 Water Quality.

Shellstock shall not be cleaned, stored, floated, or conditioned in water, the standard of which is not as rigid as that required at certified shellfish beds.

Article 7. Plants and Operations

Section T17-7738 to Section 7762 – No changes.